(11) (A) No. 1039144

(45) ISSUED 780926

(52) CLASS 137-1.50
C.R. CL. 21-45

(51) INT. CL. [2] A62B 7/00, 18/00

(19) (CA) CANADIAN PATENT (12)

(54) SHIELDED FACE MASK

(70) Scott, Arthur A.; Cooper, Joel D. and Wexler, Ronald, Canada

Granted to C. R. Bard, Inc., U.S.A.

(21) APPLICATION No. 256,737

(22) FILED 760714

(30) PRIORITY DATE

No. OF CLAIMS 4

Management of respiratory insufficiency requires knowledge and control of the inspired oxygen concentration (F_iO_2) delivered to the patient. In addition, control of the oxygen concentration administered to the patient is required if one is to avoid unnecessarily high inspired oxygen concentrations, with the attendant risk of pulmonary oxygen toxicity.

When the patient is breathing through a closed system, such as through an intratracheal tube, the inspired oxygen concentration can be easily measured and controlled. When oxygen is delivered via an open face mask, for instance, a mask having large holes in the cheek portion, the true inspired oxygen concentration cannot readily be measured and may be influenced by factors other than the oxygen concentration delivered to the mask. These variables include the patient's respiratory rate and pattern of breathing, the design and fit of the mask used, the flow rate of the oxygen delivered to the mask, and air turbulence in the area surrounding the patient.

U.S. Patent 3,850,171 to G.J. Ball et al shows a medical face mask having several apertures in the mask body. U.S. Patent 2,843,121 to C. H. Hudson also shows a mask having a large plurality of small openings in the cheek portion rather than a single large opening. In fact, U.S. Patent 2,843,121 specifically states that a series of small openings instead of one large opening in each cheek portion is desirable to prevent too free a passage of the gases in or out of the mask. U.S. Patents 1,491,674 to Coletti and 3,288,133 to Sachs, both show face masks having cheek holes covered by extensions or enclosures. However, the masks shown therein do not have means for supplying oxygen to the mask and both inhalation and exhalation is effected through these openings. The main purpose of the extensions or enclosure is to direct exhaled air away from the wearers face or to act to filter inspired air.

U.S. 3,315,672 to Cunningham et al also shows a mask with "air

reflux fairings" over cheek holes. However, these enclosures also perform a much different function than the shields of the present invention. This mask is designed for use by a surgeon and cannot be used for supplying oxygen to a patient. In the Cunningham et al mask, inhalation is through the intake valves in the cheek portion of the mask and exhalation is through an exhaust conduit positioned in front of the users mouth. The purpose of the air reflux fairings is to prevent any expired air from being directed onto a patient during any transitional period between inspiration and exhalation when the intake valves may not be completely closed against exhalation.

U.S. Patent 2,416,411 to Sharbaugh et al shows a face mask for delivery of breathable oxygen to a pilot operating at high elevations. The demand type mask includes a valve in the inlet duct, which opens only on inhalation, and valves located in the cheek portion of the mask which open on exhalation. These exhalation valves are completely enclosed by a louver which is designed to protect the valve and to retain warm exhaled air in the vicinity of the valve to prevent the valve from freezing.

None of the masks described in these patents show or suggest the mask described and claimed herein as none have, in combination,a means for administering oxygen or an oxygen containing gas stream to the mask, cheek holes which allow dilution of the oxygen in the mask and dispersion of exhaled breath from the mask with a minimum of restric tion, and open ended shields over the cheek holes to limit and/or prevent external conditions from causing the oxygen concentration which reaches the patient to be greatly different from that predicted to be delivered to the patient.

Summary of the Invention

The standard masks available for administration of oxygen or gas mixtures containing oxygen to patients have unrestricted holes in the cheeks of the mask which act 1) to dilute the oxygen fed to the patient and 2) allow exhaled breath from the patient to be dissipated. It has been found that using such masks, the percent of oxygen fed to the patient cannot be accurately controlled, high oxygen percentages cannot be administered, and there are differences between the predicted inspired oxygen concentrations (F_iO_2) clinically measured with those predicted sources. Using a completely enclosed mask, such as an anesthesia mask, or a mask with one way vents or multiple small cheek holes is not desirable because these structures cause undesirable restriction of the patients breathing pattern and the flow of gas in and out of the mask.

Clinical results obtained with the standard mask show a variation in the relationship between the clinically measured and predicted inspired oxygen concentrations (F_iO_2). Several possibilities were considered to explain these results. For instance, the respiratory pattern in the patient might change during the experiment and tidal volume during the experiment might not be the same as the tidal volume measured with the anaesthesia face mask before and after the experiment, or the mathematical model used to predict F_iO_2 might not have taken into consideration factors or variables of importance.

Accordingly, a mechanical model was constructed in order to control these variables as much as possible. However, even with the mechanical model unexpected variations in the "tracheal" oxygen concentration occurred. It became apparent that there was a significant, though unpredictable, mixing of incoming oxygen in the mask with ambient room air. This mixing, over and above that attributable to the difference between the inspiratory flow rate and the flow rate of oxygen delivered to the mask, is apparently caused

by turbulence resulting from conditions surrounding the patient such as air flow from ventilation ducts, fans or air conditioners, disturbances caused by persons passing by or administering to the patient, the patient's own movement, as well as other extraneous sources, or turbulence generated within the oxygen mask itself caused by the incoming stream of oxygen.

The shielded mask of the present invention eliminated all the adverse effects caused by turbulence, either interior or exterior of the mask.

An object of the invention is to provide a vented face mask which will deliver predictable oxygen concentrations.

Another object of the invention is to provide a vented face mask for delivery of oxygen to patient where the inspired oxygen concentration is not subject to variation caused by external sources.

An additional object of the invention is to provide a vented face mask which will allow the delivery of high oxygen concentrations to a patient.

Other objects and advantages of the invention will appear from the following description of the preferred embodiment of the invention.

Brief Description of the Drawing

Figure 1 is a side perspective view of the invention.

Figure 2 is a front perspective view of the invention

Figure 3 is a second side perspective view of the invention.

Figure 4 is a graph showing clinical results of mean inspired oxygen concentrations measured on patients using a standard mask.

Figure 5 is a schematic drawing of a mechanical model used to simulate respiration for comparison of the standard mask to the mask of the invention.

Figure 6 is a graph showing a standard mask as tested under clinical conditions compared with the same mask evaluated using the mechanical model under both turbulent and turbulence free conditions.

Figure 7 is a graph showing the results of evaluation of the mask of the invention (shielded mask) under the turbulent and turbulence free conditions, using the mechanical model.

Figure 8 is a graph comparing the standard mask and the mask of the invention (shielded mask) under non-turbulent conditions using the mechanical model.

Figure 9 is a graph showing the standard mask and the shielded masks compared under similar conditions in a controlled clinical experiment under normal hospital conditions.

Description of the Preferred Embodiment

Referring now to the drawings, the shielded mask of the present invention is shown in Figures 1 through 3. The mask 10 consists of a flexible shell shaped to fit about the nose and mouth of a patient and to be in contact with the face so as to prevent gas administered to the patient from leaking around the edges of the mask. To aid in sealing the mask to the face, a flange is provided at the outer edge of the mask. The top of the mask 14 is shaped to fit on and approximate the bridge of the nose while the lower end 16 is rounded to fit just under the patient's chin. Along the side of the mask and approximately half way between the top and bottom of the mask are a pair of tabs 18. Attached to tabs 18 is an adjustable or elastic retaining strap 20. In use, the strap 20 is placed behind the patient's head thus retaining the mask on the patient and causing the flange 12 to make intimate contact with the patient's face so that the administered oxygen does not leak around the edges of the mask.

Located in the upper part and in the center of the nose portion 21 of the mask is a pin 22. Mounted on this pin is a nose clip 24. The nose clip is a flexible material, preferably a thin metal which can be easily bent, and when bent readily retains its new shape. After the mask is placed on a patient, finger pressure placed on the nose clip 24 will bend it so that the clip and the portion of the mask underlying the clip is shaped to conform to the nose of the patient, thus effecting a good seal between the mask and the patient's face surrounding the nose.

Attached to the lower end of the nose portion 21 is an inlet part 26 sized for the attachment of an aerosol connector 28, an oxygen dilution valve (not shown) or tubing connected to a regulated source of oxygen (not shown). Located on both sides of the nose portion 21 are a pair of cheek holes 28 which allow expired air to leave the mask and which allow diffusion of ambient air to dilute a concentrated oxygen stream administered through the inlet port 26. The cheek holes are preferably about 1/2 inch to 1 inch in diameter but the size of the holes are not believed to be critical. In addition,

rather than a single large hole on either side of the nose portion several holes or a series of holes having a cross-sectional area approximately the same as the single cheek hole 28 would serve the same purpose as each of the single cheek holes 28. Positioned over the cheek holes 28 are shields 30. As shown in Figure 3 shields 30 are cup shaped flexible enclosures which cover but do not obstruct the cheek holes 28. The lower portion of the shields 32 are open to allow easy diffusion or flow of gases in and out of the mask while the upper portion of the shields prevent flow of air outside or past the mask from disturbing the oxygen concentration within the mask.

Using the shielded mask on patients it was possible to obtain a higher inspired oxygen concentration than was possible with the standard mask and, with the shielded mask, the tracheal oxygen concentration could be raised to 100% with a sufficiently high flow rate of oxygen delivery, also not possible with the unshielded mask. In addition, the concentration of the inspired oxygen could be more readily and accurately regulated. Greater standard deviations at delivered flow rates of less than 15 litres per minute were obtained using the shielded mask but this probably represents true breath-to-breath variations in a situation where the delivered oxygen flow does not approximate inspiratory flow requirements.

EXAMPLE 1

Intratracheal oxygen concentration was directly measured in patients receiving oxygen by the use of a face mask having holes in the cheek portion thereof. Each patient had had a tracheostomy tube removed several days earlier but was breathing spontaneously through the upper airway with the residual stoma covered by an occlusive dressing. A catheter was passed through this stoma into the distal trachea through a small plastic plug which completely occluded the rest of the stoma. The intratracheal catheter was connected to a small Y connector. One limb of the Y connector was used for withdrawing samples of tracheal gas for oxygen analysis. The other limb was connected to a CO_2 analyzer set to sample at 500 c.c. per minute. The output of the CO_2 analyzer was continuously recorded on a strip chart recorder.

The total volume of the catheter Y piece and connecting tubing was 3.5 c.c.

100% oxygen was delivered to the patient through a nebulizer using calibrated flow meters. Wide bore tubing (3/4") connected the nebulizer to a standard aerosal oxygen mask, which was substantially as shown in Figure 1 except that the cheek shields were not present. An example of such a mask is sold as Cat. No. 002610 by Inspiron Division of C.R. Bard, Inc.

The continuous recording of the CO_2 concentration in the trachea served as a tracing of the respiratory cycle and permitted measurement of the respiratory rate and the duration of the inspiratory phase of each respiratory cycle (the inspiratory fraction).

Samples of tracheal gas for oxygen analysis were aspirated through the limb of the Y connector used to withdraw samples into 50 c.c. plastic syringes during several consecutive inspiratory cycles at a time when respiration was stable and the sampled gas was immediately analyzed using a paramagnetic oxygen analyzer.

In each patient the flow rate of 100% oxygen delivered to the mask was successively raised from 5 litres per minute to 30 litres per minute in 5 litre increments. At each of these six flow rates, tracheal oxygen concentration was measured during the inspiratory phase.

The patient's minute ventilation was measured with a respirometer attached to an occlusive anaesthetic face mask, both immediately before and immediately after the measurements of the tracheal oxygen concentrations delivered by the plastic face mask. The duplicate values of minute ventilation proved to be quite similar, with the difference between the two being less than 600 c.c. in each patient. The average of the two minute ventilation determinations was used for subsequent calculations. Tidal volume was calculated by dividing the minute ventilation by the respiratory frequency.

Figure 4 shows results obtained in clinical studies using the standard

face mask. The tracheal oxygen concentration increases with increasing flow rates of delivered oxygen as would be expected. However, even at high flow rates, there is marked variation in F_iO_2 from patient to patient (as reflected by the standard deviation). In addition, tracheal oxygen concentration never reaches 100% but rather appears to plateau as the flow rate of oxygen to the mask is increased. In addition, it was believed that the environment surrounding the patient was affecting the amount of oxygen actually delivered to the patient.

To evaluate the effect of the variables which might affect the inspired oxygen concentration in patients, a mechanical model of the ventilatory system was constructed as shown in Figure 5. A sine-wave pump 34 was used to simulate respiration. A standard plastic aerosal mask 36 as described above was mounted on a firm backing 38 and attached to the pump 40 with a tube the size of a normal human trachea. A catheter 42 was used to sample the F_iO_2 in the mechanical "trachea". 100% oxygen 41 was delivered through the same system of flow meters 43 and nebulizer 44 used for the clinical studies. The pump was set to deliver a tidal volume of 600 c.c. at a respiratory frequency of 15 cycles per second and an inspiratory fraction of 0.5 of the respiratory cycle. Oxygen flow rates to the mask were varied from 5 litres to 30 litres per minute as in the clinical studies. In addition the studies using the mechanical model were carried out in both a very still environment and in one containing air currents generated by a small fan placed 6 feet from the face mask and the effect of turbulence caused by the fan was determined. The test was then repeated using the modified oxygen mask having shields over the side-holes as illustrated in Figure 1.

Figure 6 shows the result obtained with the mechanical model using the standard face mask in both a still and a turbulent environment. In the turbulent environment, (with the fan on), the F_iO_2 varies considerably and unpredictably. In the still environment (fan off), the F_iO_2 is higher and more stable. However, in neither case did the oxygen concentration in the mechanical trachea reach 100% even with oxygen delivered to the face mask at a rate

of 30 litres per minute. For comparison purposes the result of the clinical trial shown in Figure 5 is also incorporated in Figure 6. As can be seen, the clinical situation is neither a still or turbulent condition but is instead an intermediate condition.

Results obtained under similar circumstances with the shielded mask of the invention, are shown in Figure 7. These figures illustrate two important features of the modified mask. The first is that room air turbulence has no significant effect on the F_iO_2 delivered with this mask. The second is that the F_iO_2 delivered with this mask is higher at any given flow rate of oxygen delivery than the F_iO_2 measured under similar circumstances with the unshielded mask. With the shielded mask, inspired oxygen concentration in the mechanical trachea reaches 100% at an oxygen flow rate of 30 litres per minute. Even in the still environment, the F_iO_2 delivered with the shielded mask is higher than with the unshielded mask under similar circumstances. The results for the mask with shields and the standard mask evaluated under still conditions are shown in Figure 8.

Using both the shielded and standard mask on each patient clinical measurements of tracheal oxygen concentration were obtained. The results of this study, shown in Figure 9, demonstrate that the F_iO_2 obtained with the shielded mask is consistently higher than that obtained with the standard mask under similar circumstances and values approaching 100% F_iO_2 could only be attained using the shielded mask. In addition, when oxygen flow to the mask is 15 litres per minute or greater, the standard deviation from patient to patient using the shielded mask, is significantly less than the standard deviation from patient to patient with the standard mask ($P < .005$), indicating that the shields reduced disturbances of the oxygen feed caused by outside sources.

WHAT IS CLAIMED IS: 1039144

1. A breathing mask comprising a flexible shell sized to enclose the nose and mouth of a patient, the outer edge of said shell shaped to correspond to the contours of a patient's face, said shell having an inlet port and at least one open unrestricted outlet port opening freely through the shell, and an adjustable strap attached to said shell to hold the shell on the patient's face and to cause the edge of the shell to make intimate contact with the patient's face, the improvement comprising at least one raised shield attached to the shell about a substantial portion of the outlet port, said shield overlying the outlet port in outwardly spaced relation thereto, the shield opening laterally of the outlet port for a shielding of the open outlet port from air turbulence or the like while maintaining unrestricted communication of the interior of the shell with the ambient air.

2. The mask of claim 1 wherein the shell includes a raised nose portion, two outlet ports in the shell, said ports spaced on each side of the nose portion, and two raised open-ended shields attached to the shell, one shield covering each of the outlet ports.

3. The mask of claim 1 wherein the shell includes a raised nose portion, at least one outlet port in the shell on each side of the nose portion and a pair of raised open-ended shields attached to the shell, such that one shield covers the outlet ports in the shell on one side of the nose portion and the second shield covers the outlet ports in the shell on the other side of the nose portion.

4. The mask of claims 1, 2 or 3 including means for administering oxygen or an oxygen containing gas stream through said inlet port to the wearer of the mask.

4-1

FIG. 1

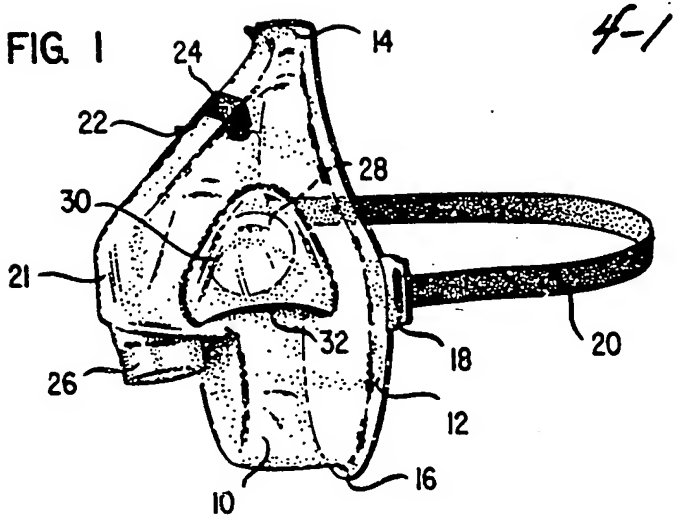


FIG. 2

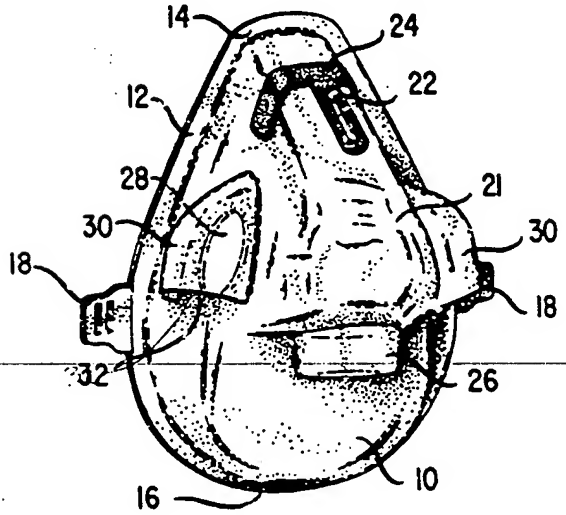


FIG. 3

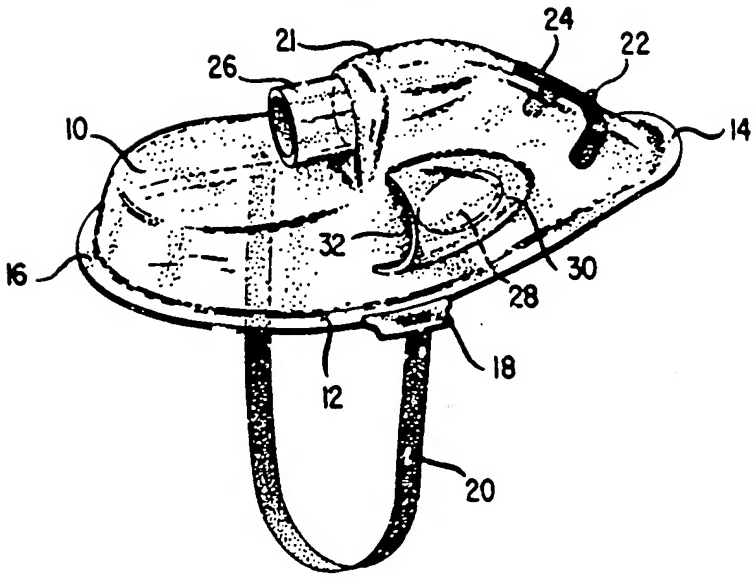


FIG. 4

CLINICAL RESULTS USING STANDARD MASK IN TEN PATIENTS

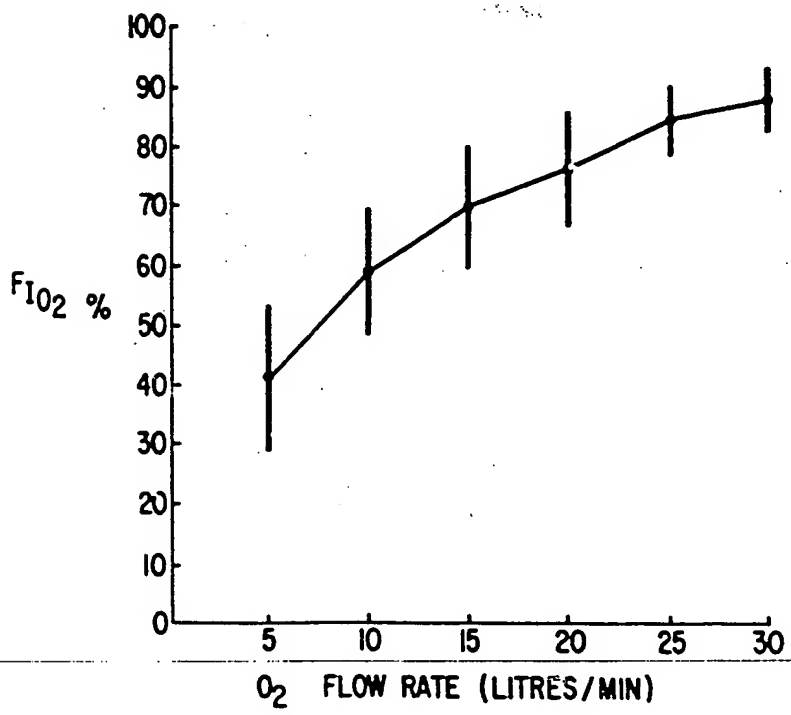


FIG. 5

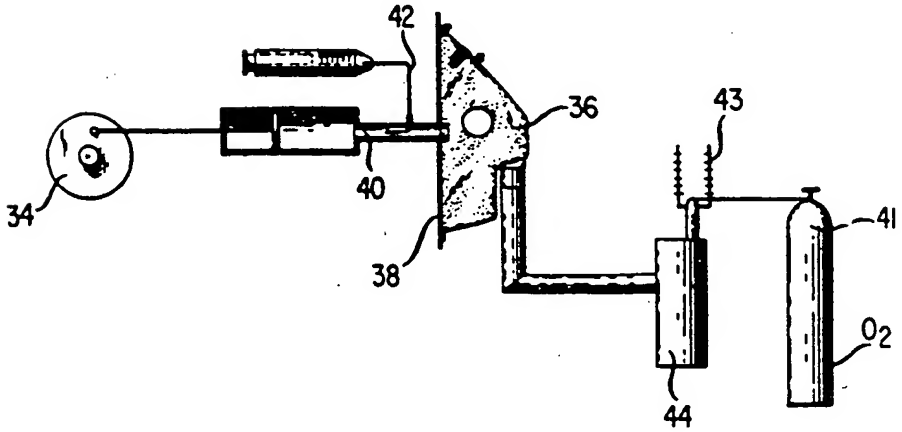


FIG. 6

4-3

MECHANICAL MODEL STANDARD MASK
TURBULENT & STILL CONDITIONS

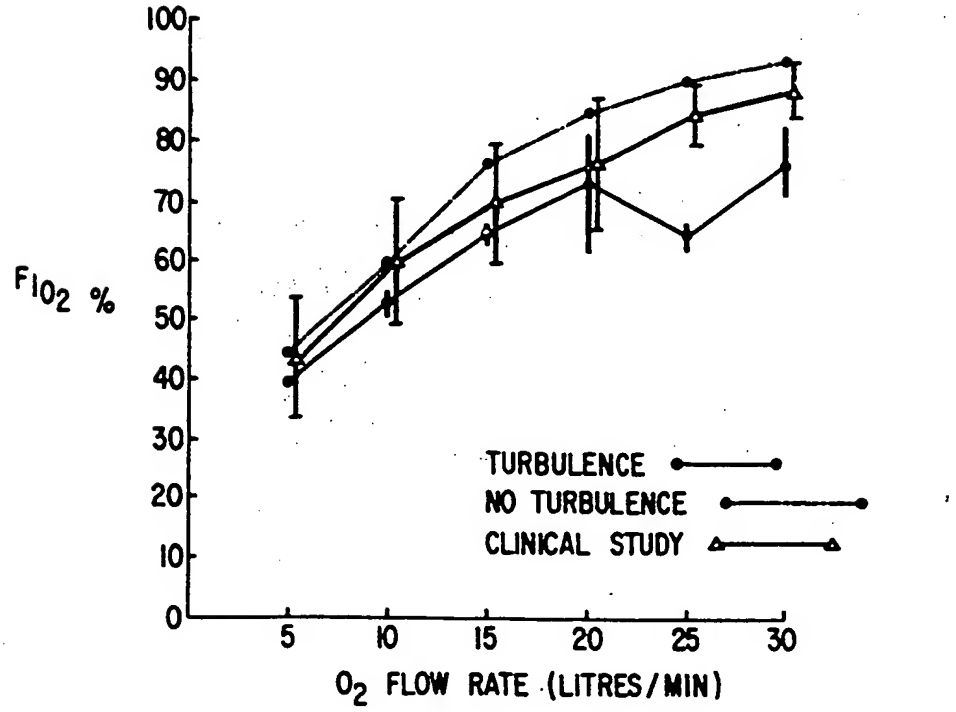
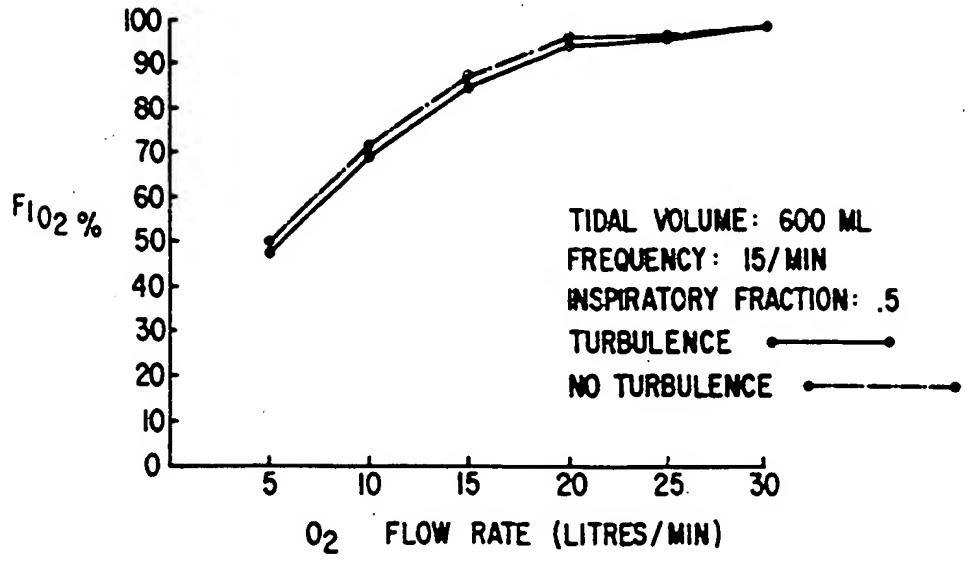


FIG. 7

MECHANICAL MODEL MASK WITH SHIELDS
TURBULENT & STILL CONDITIONS



4-4

FIG. 8

MECHANICAL COMPARISON OF AEROSOL MASK & SHIELDED MASK IN NON-TURBULENT ENVIRONMENT

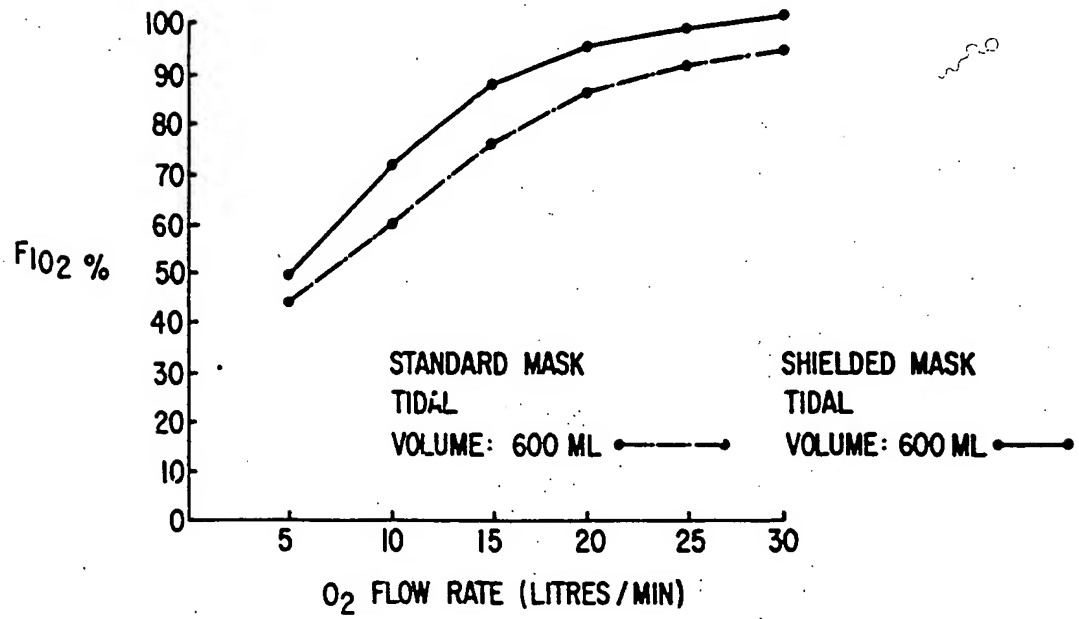


FIG. 9

STANDARD & SHIELDED MASK
MEAN INSPIRED OXYGEN CONCENTRATIONS
(CLINICAL EVALUATION - 5 PATIENTS)